

### **REMARKS/ARGUMENTS**

Claim 52 has been revised to feature a specific synthetic retinoid as disclosed in Figure 1B and in the specification at least on page 3, paragraph [0011]; pages 3-4, paragraph [0013]; page 4, paragraphs [0016] and [0017]; pages 4-5, paragraph [0018]; page 5, paragraphs [0020] and [0020]; and Example 1, beginning on page 16.

Independent Claim 53 and dependent Claims 63-71 have been canceled without prejudice for re-presentation in a continuing application.

The claim revisions and cancellations are made for business reasons rather than any issue of patentability alleged in the Office Action mailed August 25, 2010. Applicants expressly reserve the right to re-present subject matter, removed from the claims by the above revisions, in a continuing application without prejudice.

No new matter has been introduced, and entry of the revised claims is respectfully requested.

#### **No new issue for search or consideration**

The above revisions to the claims leave them with the feature of an 11-*cis*-7-ring retinal compound which was expressly indicated as enabled in the Action mailed August 25, 2010 (see last paragraph on page 7 and first paragraph on page 8 of the Action). This indicates that the subject matter of the revised claims must have been searched and examined, so no new issue for search or consideration is presented by the revised claims. This is also consistent with the original election of 11-*cis*-7-ring retinal (via the response filed February 8, 2008) in response to a Requirement for Election of Species.

#### **Alleged rejections under 35 U.S.C. § 112, first paragraph**

Claims 52 and 54-62 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants have carefully reviewed the statement of this rejection and respectfully point out that the basis for this rejection is on the *in vivo* assay conditions previously featured in Claim 52.

As provided above, Claim 52 no longer includes the *in vivo* assay conditions, and so this rejection may be properly withdrawn.

Claims 53 and 63-71 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement due to the presence of “new matter.” Applicants respectfully point out that these claims have been canceled without prejudice for re-presentation in a continuing application.

Therefore, this rejection may be properly withdrawn.

Claims 52 and 54-62 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement due to a lack of description of conditions encompassed by the P23H mutation. Applicants respectfully point out that these claims have been canceled without prejudice for re-presentation in a continuing application.

Therefore, this rejection may be properly withdrawn.

Claims 52-71 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly enabled only for particular retinal compounds. Applicants have carefully reviewed the statement of this rejection and respectfully point out that the above-revised claims are limited to a single retinal compound, by structure, identified as enabled on pages 7 and 8 of the Action mailed August 25, 2010.

Therefore, this rejection may be properly withdrawn.

*Alleged rejections under 35 U.S.C. § 112, second paragraph*

Claims 52 and 54-62 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite due to the term “derivative” in independent Claim 52. Applicants respectfully point out that above-revised Claim 52 no longer include use of this term, and so this rejection may be properly withdrawn.

Claims 53 and 63-71 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite due to a lack of description of conditions encompassed by the P23H

mutation. Applicants respectfully point out that these claims have been canceled without prejudice for re-presentation in a continuing application.

Therefore, this rejection may be properly withdrawn.

Alleged rejections under 35 U.S.C. § 103

Before addressing the rejections of record, Applicants acknowledge the indication on page 16 of the Action mailed August 25, 2010 regarding the treatment of Chapple et al. (“Looking at protein misfolding neurodegenerative disease through retinitis pigmentosa” ANCR, 3(1):12-13, 2003) as applicable as art under 35 U.S.C. § 102(a). Accordingly, Applicants expressly reserve the right to obviate the applicability of Chapple et al. as art under 35 U.S.C. § 102(a).

Claims 52-54, 60, 62-63, 69, and 71 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Chapple et al. (“Looking at protein misfolding neurodegenerative disease through retinitis pigmentosa” ANCR, 3(1):12-13, 2003) in view of Asato et al. (“Fluorinated rhodopsin analogues from 11-fluoro and 14-fluororetinal” JACS, 100(18):5957-5960, 1978). Applicants have carefully reviewed the statement of the rejection as well as the cited documents and respectfully traverse because no *prima facie* case of obviousness is present with respect to the above-presented claims.

Applicants respectfully point out that neither Chapple et al. nor Asato et al. teach or suggest an 11-*cis*-7-ring retinal with the structure now present in Claim 52. As indicated in Figure 1B and Example 1 of the instant application, there are four isomers of 11-*cis*-7-ring retinal, and Claim 52 only features isomer 3. There is no disclosure or suggestion in Chapple et al. or Asato et al., whether each is taken alone or in combination, of the retinal now featured in Claim 52.

Without any teaching or suggestion of an express feature in Claim 52, no *prima facie* case of obviousness is possible, and this rejection may be properly withdrawn.

Claims 55 and 64 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Chapple et al. (as cited above) in view of Asato et al. (as cited above) and Grant et al. (“Treatable forms of Retinitis Pigmentosa with systemic neurological disorders”). Applicants have carefully reviewed the statement of the rejection as well as the cited documents and respectfully traverse because no *prima facie* case of obviousness is present with respect to the above-presented claims.

Applicants respectfully point out that Claim 64 has been canceled without prejudice and that this rejection suffers from the same deficiencies in Chapple et al. and Asato et al. as explained above. Dependent Claim 55 has the same 11-*cis*-7-ring retinal structural feature present in revised Claim 52. There is no disclosure or suggestion in Chapple et al. or Asato et al., whether each is taken alone or in combination, of the retinal now featured in Claim 52.

Like Chapple et al. and Asato et al., Grant et al. fails to teach or suggest the retinal featured in Claim 55, regardless of whether Grant et al. is taken alone or in any combination with Chapple et al. and/or Asato et al.

Without any teaching or suggestion of an express feature in Claim 52, no *prima facie* case of obviousness is possible against Claim 55, and this rejection may be properly withdrawn.

Claims 56-59, 61, 65-68, and 70 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Chapple et al. (as cited above) in view of Asato et al. (as cited above) in view of Lang et al. (“Ocular drug delivery conventional ocular formulations”) and Geroski et al. (“Drug delivery for posterior segment eye disease”) Applicants have carefully reviewed the statement of the rejection as well as the cited documents and respectfully traverse because no *prima facie* case of obviousness is present with respect to the above-presented claims.

Applicants respectfully point out that Claims 65-68 and 70 have been canceled without prejudice and that this rejection suffers from the same deficiencies in Chapple et al. and Asato et al. as explained above. Dependent Claims 56-59 and 61 have the same 11-*cis*-7-ring retinal structural feature present in revised Claim 52. There is no disclosure or suggestion in

Chapple et al. or Asato et al., whether each is taken alone or in combination, of the retinal now featured in Claim 52.

Like Chapple et al. and Asato et al., neither Lang et al. or Geroski et al. teach or suggest the retinal featured in Claim 55, regardless of whether Lang et al. and Geroski et al. is each taken alone or in any combination with Chapple et al. and/or Asato et al.

Without any teaching or suggestion of an express feature in Claim 52, no *prima facie* case of obviousness is possible against Claims 56-59 and 61, and this rejection may be properly withdrawn.

*Alleged double patenting rejections*

Previous Claims 52-71 were *provisionally* rejected on the ground of nonstatutory obviousness-type double patenting over Claim 1 of co-pending application 11/817, 015. Applicants have carefully reviewed the statement of the rejection as well as the cited application and respectfully point out that it is inapplicable to the revised claims presented above.

The alleged basis for this rejection appears to be no more than an assertion that the claims in the co-pending application are thought to “encompass” the claims of the instant application. But this assertion is made in the total absence of any demonstration that it would have been obvious to the skilled person provided with the claims of the co-pending application to arrive at the instant claims. Similarly, there is no evidence that it would have been obvious to the skilled person provided with the instant claims to arrive at the claims of the co-pending application. In light of the lack of any demonstration or evidence, no *prima facie* case of double patenting has been presented, and this rejection may be properly withdrawn.

Additionally, Applicants observe that no substantive search or examination has yet occurred in the co-pending application. Therefore, Applicants respectfully point out that with the expected allowance of the above-revised claims, this *provisional* rejection may be properly withdrawn without prejudice to either the co-pending application or the instant application.

Appl. No. 10/801,078  
Amdt. dated September 8, 2010  
Reply to Action of August 25, 2010

CONCLUSION

In light of the foregoing, Applicants respectfully submit that the claims are allowable and urge early indication to that effect. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at number below.

Respectfully submitted,

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